

**REMARKS**

Reconsideration of the application, as amended, is respectfully requested.

The claims have been amended to place them in better form for prosecution in the United States. The "added in such a way" language has been deleted as has the "involving" language. Claim 6 has been amended to use more traditional Markush language. The term "meal replacers" has been canceled without prejudice since it is redundant with the term "dietetic products." This can be seen from page 7, line 12 of the specification. However, it is submitted that one of ordinary skill would be able to determine what "sweets," "bars," and bakery products, etc. are.

Claim 1 has now been amended so that it refers to only the step of adding non-viable bacteria (Step 1/original claim 3). The subject matter of 2 has been incorporated into claim 1. Thus claim 1 is now a combination of original claims 1 + 2 + 3. The subject matter of step II/original claim 4 has been removed from amended claim 1 and incorporated into new claim 14.

Claim 2 has been canceled without prejudice and the subject matter thereof incorporated into claim 1 and new claim 14.

The subject matter of claims 5, 6 and 7 has been made also dependent from new claim 14 in new claims 18-20.

Claim 14 is new and claims the subject matter of step II/original claim 4 + that of original claims 1 and 2.

Claim 15 is new and claims the subject matter recited on page 6, line 31 to page 7, line 4. It has been made to depend from claim 9.

The phrase "health active" in claim 2 is defined on page 6, lines 1 and 2 as "probiotics which have been rendered non-viable." It is submitted that one of ordinary skill would well be able to identify these.

The more preferred subject matter of claim 8 is now deleted from this claim and has been incorporated as new claim 12. The most preferred subject matter has also been deleted and has been incorporated as new claim 13. The comma has been inserted into product claims 9-11 as suggested by the Examiner.

Applicants note, with appreciation, allowance of product claim 9.

The Office points to Hutkins et al. as teaching the addition of non-viable bacteria to prevent spoilage of food. Claim 1 has been amended to emphasize that it is health active non-viable Lactobacillus bacteria to which the invention is directed. The Office points to no teaching that non-viable Lactobacillus bacteria which are health active should be added to foods. Likewise, new claim 14 is directed to a method to produce a food product comprising health active non-viable Lactobacillus bacteria. It will be apparent that not all Lactobacillus are health active. See, e.g., the present specification at page 6, lines 22-30.

However, the disclosure by Hutkins et al., (U.S. Patent No. 5,186,962) would not affect the novelty of the invention of claim 1 even in the absence of the recently introduced amendments. Hutkins discloses the use of live cells of non-fermenting and/or non-growing lactic acid bacteria to deliver bacteriocin into edible food substances to inhibit the growth of food spoilage and/or foodborne pathogenic organisms. Col. 3, lines 40-

59 disclose the objects of Hutkins' invention; in all cases cell growth and/or fermentation are prevented while the production of bacteriocin is required. Co. 3, line 61 to Col. 4, line 18 states that a "sufficient amount of a non-growth concentration of living bacteriocin producing lactic acid bacterial cells" is used according to the invention.

In order to achieve his invention, Hutkins teaches that the fermentation of the lactic acid bacteria can be prevented by modifying the bacteria so that it is rendered incapable of significantly fermenting the substrate (Col. 4, lines 23-27) or that unmodified bacterial cells can be used provided that the cell concentration is carefully controlled and the food substance into which the bacteria incorporated is substantially free of a substrate needed for fermentation (Col. 4, lines 46-55). Alternatively, the lactic acid bacteria containing food product is subjected to conditions which inhibit bacterial growth or fermentation, such as refrigeration or the incorporation of specific food ingredients (Col. 4, line 56 - Col. 5, line 3). The cell count or concentration of the bacteria can increase, but the levels are preferably controlled to within the ranges 10-100%, preferably 10-50% within the food mixture (Col. 5, lines 56-60 and Col. 7, line 62 to Col. 8, line 2).

The bacteria of Hutkins are thus prevented from growing or fermenting because they are maintained under conditions that inhibit their cell growth and fermentation (Col. 7, lines 7-14). However, this does not disclose, or mean, that the bacteria of Hutkins are non-viable bacteria as recited in the claims of the present invention.

Page 5, lines 10-17 of the specification of the present application indicate what is meant by the term "non-viable" as used in the present claim 1, and also what is meant by the term "viable." The Office points to no teaching that the bacteria of Hutkins are non-viable as presently recited. Especially is it clear that Hutkins' embodiments wherein the edible food is substantially free of a substrate that the lactic acid bacteria need for

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fermentation and wherein conditions which inhibit growth are imposed, are not situations in which "substantially all or all bacteria are not capable of growing under the appropriate growing conditions of said Lactobacillus strain" (instant specification description of non-viable Lactobacillus bacteria, page 5, lines 14-17).

Independent claims 10 and 11 are also novel over the disclosure and teaching of Hutkins for the same reasons as given for claim 1.

As to the obviousness rejection, the present invention is concerned with including non-viable Lactobacillus in food products and using these food products for promoting the health of human beings (see page 1, lines 6-9). This is a totally different purpose and technical field compared to that of Hutkins. The Office points to no teaching in Hutkins regarding the inclusion of Lactobacillus into food products for this reason. Thus, the invention as defined in the present claim 1 is not obvious in view of the teaching of Hutkins.

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Applicant wishes also to discuss the patentability of the amended claims over U.S. Patent No. 3,794,739 (Lee et al.) mentioned briefly in the specification.

Lee et al. disclose foods which are inoculated with lactic acid producing bacteria which have been previously been rendered non-viable, but which are still able to produce acid to safeguard against food poisoning (abstract). The bacteria are rendered non-viable by irradiation and are then added to a food product, if necessary along with a fermentable carbohydrate (Col. 1, lines 35-43). The food products may then be fermented, or, if desired fermentation is avoided by cooling the inoculated food (Col. 3, lines 42-50). Lee et al. disclose that bacteria approved for use in foods, such as Lactobacillus acidophilus and Lactobacillus plantarum may be used in their invention (Col. 1, lines 54-55).

As already discussed, claim 1 has been amended to recite that the non-viable Lactobacillus bacteria are "health-active" bacteria. Newly introduced claim 14 also has this feature. The term "health-active" is defined on page 6, lines 1-2 of the specification as "probiotics which have been rendered non-viable" and this is a term which is fully understood in the art. Thus, it is submitted that the meaning of this term is clear within claim 1.

The Office has pointed to no disclosure in Lee et al. that the Lactobacillus acidophilus and Lactobacillus plantarum bacteria used according to their invention are health-active/probiotic bacteria. Indeed, they are concerned with avoiding the growth in food products of the bacteria associated with food-poisoning. Lee et al. apparently have no interest, or intention in providing a probiotic effect to the person consuming the food product.

There are many strains of Lactobacillus acidophilus and Lactobacillus plantarum and Applicant submits that it is well known that only some bacterial strains with the genus have a probiotic effect. There can be no automatic conclusion that the strains which can be used for controlling the growth of unwanted bacteria or organisms of food can also be used to provide a probiotic effect to the consumer of the food.

Product claims 9, 10 and 11 (all amended) also recite that the food product includes a health-active bacteria. These claims are novel over the disclosure of Lee et al. for corresponding reasons to those given for independent claims 1 and 14.

Non-obviousness U.S. Patent No. 3,794,739 (Lee et al.)

Lee et al. are concerned with food safety rather than probiotic effects.

As mentioned above, Applicant submits it is well known that only some bacterial strains within the genus have a probiotic effect. Lee et al. give no indication that probiotic bacteria should be used.


Accordingly, the present invention is not rendered obvious by the teaching of Lee et al.

In the event that the discussion of the Lee patent above is considered new information requiring a further disclosure fee, please consider the information and charge any required fees to our Deposit Account No. 12-1155.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version With Markings To Show Changes Made.**"

In view of the foregoing amendment and comments, Applicant requests the Examiner to reconsider the rejection and now allow the claims.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE****In the claims:**

Please cancel, without prejudice, claims 2-4, add new claims 12-20 and amend claims 1 and 5-11 as follows:

1. (Amended) A method to produce a food product comprising health active non-viable Lactobacillus bacteria, wherein the method comprises the step of adding Lactobacillus bacteria ~~are added in such a way that~~ as non-viable Lactobacillus bacteria into the food product, and wherein ~~of no substantial fermentation of the food product by said~~ Lactobacillus bacteria will take place.

5. (Amended) Method according to claim 1 wherein the method comprises ~~involves~~ a heat-treatment step for preparation or preservation of the food product.

6. (Amended) Method according to claim 1 wherein the food product is selected from the group consisting of ~~meal-replacers,~~ soups, noodles, ice-cream, sauces, dressing, spreads, snacks, cereals, beverages, bread, biscuits, other bakery products, sweets, bars, chocolate, chewing gum, dairy products, dietetic products, and ~~dietetic products.~~

7. (Amended) Method according to claim 1 comprising ~~involving~~ the addition of a mixture of viable and non-viable Lactobacillus bacteria followed by rendering viable bacteria non-viable.

8. (Amended) Method according to claim 7 wherein the ratio of non-viable to viable bacteria is more than 2 : 1, ~~more preferred more than 5 : 1, most preferred more than 10 : 1.~~

9. (Amended) A food product having a pH of 3.8 or less, said food product comprising health active non-viable Lactobacillus bacteria and said food product being substantially non-fermented by said Lactobacillus bacteria.

10. (Amended) A food product having a pH of 5.0 or more, said food product comprising health active non-viable Lactobacillus bacteria and said food product being substantially non-fermented by said Lactobacillus bacteria.

11. (Amended) A food product having an  $A_w$  of 0.90 or less, said food product comprising health active non-viable Lactobacillus bacteria and said food product being substantially non-fermented by said Lactobacillus bacteria.

12. (New) Method according to claim 8, wherein the ratio of non-viable to viable bacteria is more than 5 : 1.

13. (New) Method according to claim 12, wherein the ratio of non-viable to viable bacteria is more than 10 : 1.

14. (New) A method to produce a food product comprising health active non-viable Lactobacillus bacteria, wherein the method comprises the step of adding viable Lactobacillus into the food product followed by inactivation of the viable Lactobacillus before substantial fermentation of the food product can take place, and wherein no substantial fermentation of the food product by said Lactobacillus bacteria will take place.

new  
claims



15. (New) Food product according to claim 9 wherein the amount of non-viable Lactobacillus bacteria in the food product is from about  $10^6$  to  $10^{11}$  per serving or per 100g of product.

16. (New) Food product according to claim 10 wherein the amount of non-viable Lactobacillus bacteria in the food product is from about  $10^6$  to  $10^{11}$  per serving or per 100g of product.

17. (New) Food product according to claim 11, wherein the amount of non-viable Lactobacillus bacteria in the food product is from about  $10^6$  to  $10^{11}$  per serving or per 100g of product.

18. (New) Method according to claim 14 wherein the method comprises a heat-treatment step for preparation or preservation of the food product.

19. (New) Method according to claim 14 wherein the food product is selected from the group consisting soups, noodles, ice-cream, sauces, dressing, spreads, snacks, cereals, beverages, bread, biscuits, other bakery products, sweets, bars, chocolate, chewing gum, dairy products, <sup>and</sup> dietetic products.

20. (New) Method according to claim 14 comprising the addition of a mixture of viable and non-viable Lactobacillus bacteria followed by rendering viable bacteria non-viable.